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Government Issues

FDA REGULATIONS - TOPLINE :

As Of May 7, 1997

Source: https://www.industrydocuments.ucsf.edu/docs/pzgn0000

Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment

I. COURT RULED THAT FDA REGULATIONS WHICH WENT INTO EFFECT ON FEBRUARY 28, 1997 REMAIN IN EFFECT PENDING APPEAL.

* Regulations which went into effect February 28, 1997, are those which:
  * Prohibit sale of tobacco products to individuals under the age of 18;
  * Require retailers to verify a purchaser's age by photographic identification.

Source: https://www.industrydocuments.ucsf.edu/docs/pzgn0000

Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

II. COURT RULED THAT FDA DOES NOT HAVE THE AUTHORITY TO REGULATE TOBACCO ADVERSTISING AND PROMOTION.

* Regulations which restrict promotion and advertising defined as those which:
  - Limit advertising to black & white text-only format;
  - Restrict trade or brand name of tobacco products;
  - Prohibit sale or distribution of brand identified promotional non-tobacco items such as hats and tee-shirts;
  - Prohibit use of brand name of tobacco products to sponsor entries, teams, sporting and other events.

Source: https://www.industrydocuments.ucsf.edu/docs/pzgn0000

Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

III. COURT LET STAND FDA ACCESS RESTRICTION REGULATIONS AND PACKAGE LABEL REGULATIONS, **BUT RULED THAT THE FDA CANNOT IMPLEMENT ANY REGULATIONS SCHEDULED TO GO INTO EFFECT ON AUGUST 28, 1997** (INCLUDING ACCESS RESTRICTION AND PACKAGE LABEL REGULATIONS) PENDING FURTHER ORDERS BY THE COURT.

* Access restrictions (scheduled to go into effect on August 28, 1997) defined as those which:
  - Prohibit the sale of tobacco products through vending machines and self service displays except in facilities where individuals under the age of 18 are not permitted;
  - Prohibit distribution of free samples; and
  - Prohibit the sale of cigarette packages containing fewer than 20 cigarettes.

Source: https://www.industrydocuments.ucsf.edu/docs/pzgn0000

Status of FDA Regulations of Tobacco Products After April 25, 1997 Court Ruling on Summary Judgment (continued)

* Package label regulations defined as those regulations which require tobacco product packages to bear the established name of the product and statement of intended use.

IV. CIGARETTE MANUFACTURERS AND THE FDA HAVE FILED PETITIONS TO APPEAL. THE APPEALS PROCESS COULD TAKE YEARS AND ULTIMATELY MAY RESULT IN A TRIAL ON THE ISSUE OF WHETHER THE FDA HAS JURISDICTION OVER CIGARETTES AS CUSTOMARILY MARKETED.

AS FURTHER DEVELOPMENTS OCCUR WE WILL ADVISE YOU.

Source: https://www.industrydocuments.ucsf.edu/docs/pzgn0000